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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/717,746	11/21/2000	Herbert M. Dean		1955

23580 7590 01/31/2002

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EXAMINER
JAGOE, DONNA A

ART UNIT	PAPER NUMBER
1614	

DATE MAILED: 01/31/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application N .	Applicant(s)	
	09/717,746	DEAN ET AL.	
	Examiner	Art Unit	
	Donna A. Jagoe	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period f r Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-13* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-13* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *2 and 3* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Claims 1-13 are presented for examination.

Claim Objections

Claim 7 is objected to because of the following informalities: metoprolol is misspelled. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 9-13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 9 rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap between the elements. See MPEP § 2172.01. The omitted elements are: the subject being treated for cardiovascular disease. The claim is drawn to a method of treating cardiovascular disease comprising formulating a dosage unit. It appears that the claim is drawn to a method of making the medicament rather than a method of treating the cardiovascular disorder. Amending the claim to recite "a method of making a medicament for treatment of cardiovascular disease comprising formulating a single dosage unit comprising a beta-adrenergic blocking agent and a platelet inhibitor" would obviate the rejection.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1-7, 9-11 and 13 are rejected under 35 U.S.C. 102(a) as being anticipated by Powell et al. U.S. Patent No. 6,140,319 A.

The claims are drawn to compositions comprising a beta blocker such as atenolol, propranolol, timolol and metoprolol and a platelet inhibitor such as aspirin. Powell et al. teach a single dosage unit of a vasopeptidase inhibitor combined with a beta blocker and an antiplatelet agent (column 2, lines 5-13). Although the ingredients of the patent include the vasopeptidase inhibitor, the broad claim language *comprising* leaves the claim open for the inclusion of unspecified ingredients, even in major amounts. Powell et al. teach the compositions useful for cardiovascular disorders such as angina pectoris (column 1, line 66 to column 2, line 1). Beta-blockers contemplated for the invention of the patent include agents such as propranolol, timolol, metoprolol and atenolol and antiplatelet agents such as aspirin (column 4, lines 6-28).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Weissman et al. U.S. Patent No. 6,121,249 A and Hansson et al. (AB).

The claims are drawn to compositions comprising a beta blocker such as atenolol, propranolol, timolol and metoprolol and a platelet inhibitor such as aspirin and optionally one or more of folic acid, vitamin B6 and vitamin B12 and method of formulating such medicaments for cardiovascular disorders.

Weissman et al. teach acetylsalicylic acid (aspirin) combined with at least one of cyanocobalmin (vitamin B12), a folic acid compound, and a pyridoxine compound (vitamin B6) (see abstract). It does not teach the addition of a beta blocker.

Hansson et al. teach the combination of aspirin and a beta blocker to be useful for treatment of hypertension (a cardiovascular disorder)(see abstract). It does not teach the addition of B vitamins such as folic acid, B12 and B6.

Weissman et al. teach that the three B-vitamins, folate and vitamins B6 and B12 play essential roles as cofactors in homocystine metabolism (homocystine increased the formation of highly atherogenic oxycolesterols, increases lipid peroxidation and increases the oxidation of LDL in vitro (column 2, lines 15-17)). Elevated plasma homocystine can be normalized by moderate vitamin supplementation. Folic acid alone, folic acid combined with B12 and B6 and vitamins B6 and B12 have all been shown to reduce homocystine concentrations. (column 2, lines 30-43). It is prima facie obvious to combine two compositions, each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose. *In re Kerkhoven* 205 USPQ 1069. The idea for combining said compositions flows logically from their having been individually taught in the prior art. *In re Crockett* 126 USPQ 186, 188. See also *In re Shannon* 148 USPQ 504 (one step laminate is obvious from two step laminate).

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Donna A. Jagoe whose telephone number is (703) 306-5826. The examiner can normally be reached on 6:30 A.M. - 3 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel can be reached on (703) 308-4725. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3230 for regular communications and (703) 308-7921 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0193.

SHEP K. ROSE
PRIMARY EXAMINER
GROUP 1200

dj
January 28, 2002